UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,542	05/26/2005	Roger Petrus Gerebern Vandecruys	PRD-2017f PCT US	7079

45511 7590 03/17/2009

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
03/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,542	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-67* is/are pending in the application.

4a) Of the above claim(s) *43-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/28/09, 1/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response and Amendment filed on 01/05/2009; and Information Disclosure Statements filed on 01/28/2009 and 01/24/2006.

- Claims 1-20 have been cancelled.
- Claims 21-67 have been added.
- Claims 21-67 are pending in the instant application.
- Claims 43-67 are withdrawn from consideration.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
>
> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data

sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be "material to patentability as defined in 37 CFR 1.56."

It does not identify the citizenship of each inventor.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Election/Restrictions

Applicant's election of Group II (claims drawn to a composition comprising a basic drug, which is new claims 21-42) in the reply filed on 01/05/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 21, the phrase "at least 1:1 by weight" it is unclear? For example, would more than 1:1 by weight be 2:1 or 1:2? Please clarify.

Regarding claim 27, the 10th edition of the Merriam-Webster's Collegiate Dictionary (Merriam-Webster Incorporated: Springfield, Massachusetts, 1993, pp 311) defines "derivative" as, "a chemical substance related structurally to another substance and theoretically derivable from it." For example, carbon dioxide could theoretically be derived from the combustion of chitin. Therefore, the definition of derivative in the Merriam-Webster Collegiate Dictionary does not shed light on what Applicants' intended for the meaning of a chitin derivative.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by SINGH et al (US 2001/0049366).

Applicant's claims are directed to a composition comprising of: a basic drug compound; vitamin E-TPGS; water-soluble acid, such as citric acid, wherein the

acid:drug ratio is at least 1:1 by weight; organic polymer, such as polyalkylene oxide or poloxomers. Additional limitations include: intimately admixed; solid dispersion; bulking agents; adapted for the mouth.

CHEN teaches a composition comprised of: a basic and water-insoluble drug compound, such as paclitaxel (see col. 20, line 32 and Title) or ciprofloxacin or AIDS drugs (see col. 7, line 28 and line 43); vitamin E-TPGS (see col. 20, line 33); water-soluble acid, such as citric acid (see col. 20, line 36), wherein the acid:drug ratio is 0.1-1%:0.1-1% (see col. 20, Example 11), which reads on at least 1:1 by weight; organic polymer, such as polysorbate 20 (see col. 20, line 34), which is an polyalkylene oxide, or poloxamers (see col. 23, line 56). Additional limitations include: mixture (see col. 3, line 58), which would read on intimately admixed; tablet (see col. 22, line 8), and suspension (see col. 22, line 9), which would read on solid dispersion; fillers (see col. 21, line 8), which would read on bulking agents; oral (see col. 21, line 21), which would read adapted for the mouth; amount of Vitamin E-TPGS could be 1-94% (see col. 20, Example 11) of the composition.

Note, the viscosity is an inherent property of the polymer; thus, the polymer of the prior art must have the same viscosity as claimed by Applicant, since it is the same polymer as claimed by Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over VERRECK et al (WO 01/22938) in view of CHEN et al (US 6,828,301) and CLANCY et al (WO 97/02017).

Applicant's claims are directed to a composition comprising of: a basic drug compound, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile; vitamin E-TPGS, which is a surfactant; water-soluble acid, such as citric acid, wherein the acid:drug ratio is at least 1:1 by weight; organic polymer, such as hydroxypropyl methylcellulose (herein after "HPMC"). Additional limitations include: intimately admixed; solid dispersion; adapted for the mouth bulking agents; tablet.

VERRECK teaches a composition comprising of: a basic drug compound, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile (see pg. 17, line 8-9), which is an antiviral drug;sodium lauryl sulfate (see pg. 42, line 28); water-soluble acid, such as citric acid (see pg. 10, line 5-6); organic polymer, such as HPMC (see pg. 36, line 1). Additional limitations include: mixture (see pg. 1, line 8), which would read on intimately admixed; solid dispersion (see pg. 40, line 4); tablet (see pg. 41, line 30), which would read on adapted for the mouth; diluent and fillers (see pg. 42, line 10), which would read on bulking agents.

VERRECK does not teach using a vitamin E-TPGS; or the amount of ingredients as claimed by Applicant.

CHEN teaches a composition comprised of: an antiviral drug; HPMC (see col. 15, line 20); surfactants, such as sodium lauryl sulfate and Vitamin E-TPGS (see col. 15, line 45-60), wherein the surfactants improves the dispersion and dissolution of the drug (see col. 15, line 45-46).

CLANCY teaches a solid dispersion (see pg. 8, line 25-26) composition comprised of: poorly soluble drugs (see Title); HPMC for controlling the drug release rate (see pg. 8, line 10-26); citric acid (see pg. 10, line 10-13) to further control the drug release rate (see pg. 10, line 10-12).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate Vitamin E-TPGS as a surfactant into VERRECK's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug, and reasonably would have expected success because VERRECK teaches using sodium lauryl sulfate, which is a surfactant disclosed in CHEN.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as drug release rate. Thus, absent some demonstration of unexpected results from the

claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Note, the viscosity is an inherent property of the polymer; thus, the polymer of the prior art must have the same viscosity as claimed by Applicant, since it is the same polymer as claimed by Applicant.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Patent Examiner, Art Unit 1618